

REMARKS**I. Status of Claims**

The examiner declined to consider the amendments filed in the last response allegedly because “[t]here is no antecedent basis in claim 14 for a “therapeutic” method as in the dependent claims.” As the dependent claims have contained the referenced language since their filing, the stated rationale has no relation to the proposed amendments and, thus, cannot justify the examiner’s inaction. From the record, therefore, it seems the examiner improperly dismissed applicants’ amendments and arguments out of hand. Nevertheless, applicants have filed the instant RCE to realize these amendments without further delay.

Thus, this amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 14 and 16-23 have been amended. Thus, after entering the amendments herein, claims 14, 16-23 and 25-26 will be pending.

Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

II. Rejections under 35 U.S.C. §103(a)

The examiner rejects claims 14-26 under 35 U.S.C. §103(a) as allegedly being unpatentable over Sato *et al.* and/or Kishimoto *et al.* in view of Gross *et al.* and Farkas *et al.* Applicants respectfully traverse the rejection.

The examiner is of the view that "[t]here is no question that the person of ordinary skill in the art would expect at least a reduction in symptoms due to the inhibition of IL-6 antibody, as evidenced by the primary references." Applicants respectfully disagree. In this regard, applicants believe the examiner mischaracterizes the state of the art at the priority date of the present application.

That IL-6 was used as a biomarker for pancreatitis would not have motivated those of ordinary skill in the art to treat acute pancreatitis with IL-6 antagonists with a reasonable expectation of success, as suggested by the examiner. Even if IL-6 is detected in a patient

with acute pancreatitis, the cited art does not suggest treating the disease by blocking IL-6, nor could it. For example, the enclosed publication of *Mediations of Inflammation* 3, 33-40 (1994) shows that in the GVHD mouse model, serum levels of IL-6 are increased. Blocking IL-6 with an anti-IL-6 antibody, however, does not change the severity or mortality of GVHD. In other words, a person with ordinary skill in the art at the time of the invention understood that there is no relationship between serum IL-6 concentration and therapeutic effect of blocking of IL-6.

Furthermore, as discussed previously, at the time of the invention it was known that not only IL-6 but also other cytokines relate to acute pancreatitis, and that once the cytokine network involving IL-6 and other cytokines is activated, blockage of one cytokine is compensated by other cytokines. Thus, an artisan at the time would have considered blocking a single cytokine to be ineffective in treating a disease involving said cytokine.

The cited art, therefore, does not presage the claimed invention. Accordingly, applicants request that the rejection be withdrawn.

Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application is respectfully requested.

The examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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